| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/839,946 | WILLIAMS ET AL. | |
| | Examiner | Art Unit | |
| | Tekchand Saidha | 1652 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *18 September 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *50-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *50-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 September 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## Detailed Action

1. The terminal disclaimer filed on 9.18.2007 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 6,783,965 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Rejection of claims 50-59 under the judicially created doctrine of double patenting over claims 1-30 of U. S. Patent No. 6,783,965 is accordingly withdrawn.

2. Applicants' request to reopen prosecution following Decision on Appeal under 35 U.S.C. § 134 of the Board of Patent Appeals and Interferences dated July 18, 2007, and as provided under 37 C.F.R. § 41.50(b)(1), is acknowledged.

3. Claims 50-61 are under consideration.

4. New Matter added to claims - [New Matter rejection]

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 50-61 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant's addition [new matter] of ' greater than 90%' in claim 50; ' greater than 95%' in new claim 60 and ' greater than 98%' in new claim 61 is not supported by the original

disclosure. Applicants are required to cancel the new matter in reply to this office action. The original claims and the original specification provide no basis for:

1. Greater than 90% of said uricase in tetrameric form.

2. Greater than 95% of said uricase in tetrameric form.

3. Greater than 98% of said uricase in tetrameric form.

[4. At least about 90% of said uricase in tetrameric form.

5. At least about 95% of said uricase in tetrameric form.

6. At least about 98% of said uricase in tetrameric form.]

The current claims do not recite the language of 4, 5 & 6 above. However, should the Applicants revert back to reciting said language, the claim will be rejected under 35 U.S.C. 112, first paragraph for lacking basis in the original claims and original specification.

Claims 51-59 are included in the rejection for not correcting the defect present in the base claim(s)

5. The amendment filed 9/18/2007 and 3/19/2008 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

(a) Amendment filed 9/18/2007 is an amendment to the specification, whereby paragraph starting at page 20, line 9, is replaced with the following paragraph – " The tetrameric form of uricase (molecular weight ca. 140 kDa) was purified from a solution of porcine liver uricase by preparative size-exclusion or ion-exchange chromatography, followed by analytical size-exclusion chromatography. Porcine liver

uricase was obtained from Sigma-Aldrich, St. Louis, Mo., catalog No. ~~U2350~~ U3250 or U3377; or Boehringer Mannheim, Indianapolis, Ind."

This was not part of the original specification.

(b) Amendment filed 3/19/2008, inserts Table 1, which was not part of the original application.

Applicant is required to cancel the new matter in the reply to this Office Action.

6. ***Claim Rejections - 35 U.S.C. § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 50-53 & 60-61 are rejected under 35 U.S.C. 102(b) as anticipated by Lee et al. [Science 239, 1288-1291 (1988), IDS, previously cited].

Lee et al. (1988) teach the recombinant production of full length amino acid sequence of porcine Urate oxidase (uricase) which is tetrameric and is substantially pure. Mammalian uricase is disclosed as a tetramer with subunit size of 32,000 Daltons (page 1288, column 2,first paragraph after the abstract). The reference further teaches purification to **homogeneity** of Porcine and murine urate oxidase (see, page 1289,

second column). Oxidation of uric acid to allantoin is catalyzed by urate oxidase (see abstract). Increased uric acid level, due to lack of this enzyme in man can lead to gouty arthritis (page 1288, column 2).

Applicants' claims are directed to ' tetrameric mammalian uricase, wherein ~~at least about~~ greater than 90% is in tetrameric form' . This is interpreted here to mean that more than 90% may also be present in the tetrameric form. Greater than 90% may also mean 100% or homogenous preparation. Therefore, the homogenous preparations of porcine or murine tetrameric uricase comprises the greater than 90% tetrameric form of mammalian uricase claimed. The reference therefore anticipates the claims.

7. Arguments in the BPAI decision:

As per the BPAI decision, affirming Examiner (See page 2 of the decision). The BPAI decision on page 3, paragraph 3 – states: " It is axiomatic that in order for a prior art reference to anticipate the claimed invention, it must disclose every limitation of the claimed invention, either explicitly or inherently. See In re Schreiber, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1432 (Fed. Cir. 1997). We find that Lee, when read in light of Appellants' statement of the state of the prior art as set forth in the Specification, anticipates the claimed subject matter of claim 50. Because our reasoning differs from that of the Examiner, and Appellants have not had a fair opportunity to respond to the

rejection, we designate our affirmance as a new ground of rejection. *See In re Kronig*, 539 F.2d 1300, 1302-03, 190 USPQ 425,426-27 (CCPA 1976).

The BPAI decision (page 5, paragraph 3 & 4) citing -

Page 16, lines 5-8 of the Specification, states:

Purified preparations of naturally occurring and recombinant uricases usually contain a mixture of aggregates of the enzyme, in addition to the tetrameric (140 kDa) form. The percentage of each uricase preparation that is in the tetrameric form generally varies from approximately 20% to 90%.

The Specification, as referenced by the Declaration of Dr. Sherman, thus states that uricase preparations containing up to 90% of uricase in the tetrameric form were known in the prior art. Moreover, as discussed above, claim 50 encompasses uricase preparations containing only approximately 90% of the uricase in tetrameric form. Therefore, claim 50 encompasses uricase preparations as prepared in the prior art, such as by Lee, and is thus anticipated by the prior art.

CONCLUSION

In summary, we affirm the rejection of claims 50-53 as being anticipated by Lee. Because our reasoning differs from that of the Examiner, we designate the rejection as to those claims as new grounds of rejection.

8. No claim is allowed.